

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/789,967
Inventor(s) : Joseph Anthony Klofta
Filed : February 27, 2004
Art Unit : 1628
Examiner : Michael B. Pallay
Docket No. : 8725R2R
Confirmation No. : 9429
Customer No. : 27752
Title : METHOD FOR PREPARING A LOTION FOR
RELIABLE HIGH SPEED PROCESSING ONTO A
SUBSTRATE

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

This Brief is filed pursuant to the appeal from the decision communicated in the Office Action mailed on July 8, 2011. A timely Notice of Appeal was filed on October 6, 2011.

REAL PARTY IN INTEREST

The real party in interest is The Procter & Gamble Company of Cincinnati, Ohio.

RELATED APPEALS AND INTERFERENCES

There are no known related appeals, interferences, or judicial proceedings.

STATUS OF CLAIMS

Claims 11-18 and 20-27 are rejected.

Claims 11-18 and 20-27 are appealed.

A complete copy of the appealed claims is set forth in the Claims Appendix attached herein.

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STATUS OF AMENDMENTS

No amendment was filed.

SUMMARY OF CLAIMED SUBJECT MATTER

Independent Claim 11. A method for preparing a lotion for reliable high speed processing onto a substrate, the method including the steps of providing a carrier system, mixing a premix solution including niacinamide and a material selected from the group consisting of glycerin, propylene glycol, panthenol, and mixtures thereof, at a temperature of at least 35 degrees C, and milling the premix solution into the carrier system at a temperature of at least 35 degrees C to disperse the premix solution until an average droplet diameter of the dispersed premix solution is less than 100 microns to form said lotion. (Specification, page 3, lines 1-7).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Rejection of claims 11-18 and 20-27 under 35 USC §103(a) as being allegedly unpatentable over Hammons et al. (WO 03/028776) in view of Klofta et al. (U.S. 2002/0165508).

ARGUMENTS

Rejection Under 35 USC §103(a) Over Hammons et al. (WO 03/028776) in view of Klofta et al. (U.S. 2002/0165508)

Claims 11-18 and 20-27 have been rejected under 35 USC §103(a) as being unpatentable over Hammons et al. (WO 03/028776) in view of Klofta et al. (U.S. 2002/0165508). Applicants respectfully traverse this rejection.

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. (*KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (U.S. 2007)). "Rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated

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reasoning with some rational underpinning to support the legal conclusion of obviousness." (*In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). *See also KSR*, 550 U.S. at 416 , 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval)).

Applicants' invention solves the plugging of the lotion application equipment which reduces process reliability and efficiency. Neither Hammons et al. or Klofta disclose or suggest premixing niacinamide with a material selected from the group consisting of glycerin, propylene glycol, panthenol, and mixtures thereof to form a premix, mixing the premix with a carrier system at a temperature of at least 35°C, and then milling the premix into a carrier system at a temperature of at least 35°C until the average droplet diameter of the dispersed premix is less than 100 microns. Applicants submit that the Office Action relies on mere conclusory statements and does not state an articulated reasoning with rational underpinning to support the legal conclusion of obviousness.

Applicants surprisingly found that plugging of the lotion application equipment is reduced when the lotion composition is prepared by formulating a concentrated premix solution of the niacinamide in glycerin/propylene glycol at sufficiently elevated temperatures and the solid skin treatment agent premix is milled into a carrier system. (Specification, page 27, lines 2-3). The milling can occur at a sufficiently elevated temperature of at least 35 degrees C, preferably at least 50 degrees C, and more preferably at least 70 degrees, and at high shear until the average droplet diameter in the dispersed premix solution, or premix phase, is less than 100 microns, preferably less than 50 microns, more preferably less than 10 microns. Without being bound by theory, it is believed that the small droplets produced by the high shear milling prevent the formation of large crystals or other particles in the lotion that contribute to equipment blockage. (Specification, page 26, lines 20-34).

Hammons et al. do not disclose the step of milling the premix solution into the carrier system to disperse the premix solution until an average droplet diameter of the dispersed premix solution is less than 100 microns. (Office Action, page 4). The Office Action relies on a conclusory statement stating that "such was known in the art" to

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support a rejection. (*Id*). Applicants submit that the Office Action has not shown an articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

Klofta et al. do not teach or suggest a lotion comprising niacinamide. Klofta et al. therefore do not disclose or suggest premixing niacinamide with a material selected from the group consisting of glycerin, propylene glycol, panthenol, and mixtures thereof to form a premix, mixing the premix with a carrier system at a temperature of at least 35 degrees C, and then milling the premix into a carrier system at a temperature of at least 35 degrees C until the average droplet diameter of the dispersed premix is less than 100 microns.

With regard to particle size of its skin care ingredients, Klofta et al. teach that:

Where the ingredients are insoluble in the composition, the average particle size of the ingredients plays an important role in suspending the particles in the composition without substantial agglomeration, stratification and/or settling. The particles should be substantially free of excessively large agglomerates, i.e., there is negligible amount of particles larger than 1000 microns. The average particle size of the skin care ingredients should preferably be less than about 1000 microns, more preferably less than about 100 microns, and most preferably less than about 50 microns.

(Klofta et al., [0061] (emphasis added)).

Klofta et al. thus teaches that for skin care ingredients that are insoluble in its compositions, such as zinc oxide, the average particle size of the skin care ingredients should be less than 1000 microns to avoid substantial agglomeration, stratification and/or settling. Klofta et al. thus do not teach or suggest appropriate particle size ranges for skin care ingredients that are not insoluble.

Niacinamide is not typically considered to be an insoluble material, especially in comparison to a material such as zinc oxide utilized by Klofta et al. In the present invention, niacinamide is somewhat soluble in the carrier system of the present lotion at elevated temperatures (e.g. 35 degrees C) and less soluble in the carrier system at ambient temperature. Niacinamide thus tends to crystallize in the carrier system upon cooling to

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ambient temperature. This crystallization can lead to problems such as instability of the lotion composition or clogging of manufacturing equipment when applying the lotion to substrates such as absorbent articles. However, premixing the niacinamide with a material selected from the group consisting of glycerin, propylene glycol, panthenol, and mixtures thereof to form a premix, mixing the premix with a carrier system at a temperature of at least 35 degrees C, and then milling the premix into a carrier system at a temperature of at least 35 degrees C until the average droplet diameter of the dispersed premix is less than 100 microns tends to minimize the formation of niacinamide crystals in the lotion at ambient temperature. This results in a lotion composition that is stable, readily processable on commercial systems for application to absorbent articles without clogging, and has improved aesthetics. The presently claimed method and its resultant benefits are not taught or suggested in the cited references and thus Applicants submit that the presently claimed invention is not obvious over the cited references.

Applicants therefore submit that the cited references do not, alone or in combination, render obvious the presently claimed invention. As such, Applicants submit that Claims 11-18 and 20-27 are patentable under 35 U.S.C. §103(a) over Hammons et al. and Klofta et al.

SUMMARY

In view of all of the above, it is respectfully submitted that the rejections of record should be reversed.

Respectfully submitted,

THE PROCTER & GAMBLE COMPANY

/AEV/

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CLAIMS APPENDIX

11. A method for preparing a lotion for reliable high speed processing onto a substrate, the method comprising the steps of:
 - (a) providing a carrier system;
 - (b) mixing a premix solution comprising niacinamide and a material selected from the group consisting of glycerin, propylene glycol, panthenol, and mixtures thereof, at a temperature of at least 35 degrees C; and
 - (c) milling the premix solution into the carrier system at a temperature of at least 35 degrees C to disperse the premix solution until an average droplet diameter of the dispersed premix solution is less than 100 microns to form said lotion.
12. The method of Claim 11, wherein the carrier system comprises petrolatum.
13. The method of Claim 12, wherein the carrier system further comprises fatty alcohols having 12 to 24 carbon atoms, alkyl ethoxylates, fumed silica, talc, bentonites, hectorites, calcium silicates, magnesium silicates, magnesium aluminum silicates, zinc stearates, sorbitol, colloidal silicone dioxides, spermaceti, carnuba wax, beeswax, candelilla wax, paraffin wax, microcrystalline wax, castrol wax, ceresin, esparto, ouricuri, rezowax, polyethylene wax, C12-C24 fatty acids, polyhydroxy fatty acid esters, polyhydroxy fatty acid amides, polymethacrylate polymers, polymethacrylate and styrene copolymers, or combinations thereof.
14. The method of Claim 12, wherein the carrier system further comprises a skin treatment active selected from the group consisting of allantoin, aluminum hydroxide gel, calamine, cysteine hydrochloride, racemic methionine, sodium bicarbonate, Vitamin C, serine protease, metalloprotease, cysteine protease, aspartyl protease, peptidase, phenylsulfonyl fluoride, lipase, diesterase, urease, amylase, elastase, nuclease, guanidinobenzoic acid and its salts and derivatives, chamomile, and mixtures thereof.

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15. The method of Claim 11, wherein the solution is mixed at a temperature of at least 50 degrees C.
16. The method of Claim 11, wherein the solution is mixed at a temperature of at least 80 degrees C.
17. The method of Claim 11, wherein the milling is at a temperature of at least 50 degrees C.
18. The method of Claim 11, wherein the milling step continues until the average droplet diameter of the dispersed premix solution is less than 50 microns.
20. A disposable absorbent article comprising a lotion made according to the method of Claim 11, wherein said disposable article is selected from the group consisting of diapers, sanitary napkins, panty liners, and incontinence briefs.
21. The method of Claim 11, wherein said method further comprises the step of spraying, extruding, or slot coating said lotion onto said substrate.
22. The method of Claim 11, wherein said niacinamide is acidified niacinamide.
23. The method of Claim 11, wherein said material of said premix solution is selected from the group consisting of glycerin, propylene glycol, and mixtures thereof.
24. The method of Claim 23, wherein said material of said premix solution is glycerin.
25. The method of Claim 11, wherein said lotion further comprises chitosan or chitosan derivative.

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26. The method of Claim 21, wherein said premix solution is added to the carrier system at a temperature of 60 to 90 degrees C.

27. The method of Claim 21, wherein said premix solution is added to the carrier system at a temperature of 70 to 90 degrees C.

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EVIDENCE APPENDIX

None.

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RELATED PROCEEDINGS APPENDIX

None.